

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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LABORATOIRES CARILÈNE S.A.S.,		:	
		:	
		:	
	Plaintiff and	:	No. 07 CIV 9616
	Counterclaim Defendant,	:	(GEL) (JCF)
		:	
	v.	:	
		:	
AUGIRA LABORATORIES, INC.,		:	ANSWER AND
		:	COUNTERCLAIMS
		:	
	Defendant and	:	
	Counterclaim Plaintiff.	:	
		:	ECF Filed
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Auriga Laboratories, Inc. (“Auriga”), by its undersigned attorneys, as and for its answer to the Complaint and counterclaims against Laboratoires Carilène S.A.S. (“Carilène”) herein, states with respect to the numbered paragraphs of the Complaint as follows:

1. Admits that Auriga and Carilène entered into a license agreement (“the Agreement”) dated September 13, 2006, and refers to the Agreement for the pertinent terms thereof, but denies all remaining allegations of paragraph 1 of the Complaint.
2. Admitted.
3. Admitted.
4. Admits that it transacts business in the State of New York, refers to the Agreement for provisions concerning jurisdiction and venue, but denies all remaining allegations of paragraph 4 of the Complaint.
5. Admitted.
6. Admitted.
7. Admitted.

8. Admits paragraph 8 except denies that Carilène has a obtained a U.S. patent that recites “the Product” (as defined in the Agreement).

9. Admitted.

10. Admitted.

11. Admits that the parties entered into the Agreement, and refers to the Agreement for the pertinent terms thereof.

12. Refers to the Agreement for the pertinent terms thereof.

13. Admits that Carilène has shipped to Auriga trade units of the Product, but denies the remaining allegations of paragraph 13 of the complaint.

14. Denied.

15. Admits that Auriga made a payment of \$250,000 to Carilène, but denies all remaining allegations of paragraph 15 of the Complaint.

16. Denied.

17. Refers to the Agreement for the pertinent terms thereof.

18. Refers to the Agreement for the pertinent terms thereof.

19. Refers to the Agreement for the pertinent terms thereof.

20. Admits that Carilène has shipped to Auriga trade units of the Product, but denies all remaining allegations of paragraph 20 of the Complaint.

21. Admits that Auriga made certain payments to Carilène for the Product, but denies all remaining allegations of paragraph 21 of the Complaint.

22. Refers to the Agreement for the pertinent terms thereof.

23. Denies that Auriga defaulted under the Agreement, and refers to Exhibit B to the Complaint for the contents thereof.

24. Denies that Auriga defaulted under the Agreement, and refers to Exhibit C of the Complaint for the contents thereof.

25. Denies that the Agreement has been lawfully terminated, and refers to Exhibit D to the Complaint for the contents thereof.

26. Denied.

27. Refers to the Agreement for the pertinent terms thereof.

28. Denied.

29. Repeats and incorporates by reference paragraphs 1 through 28 above.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Repeats and incorporates by reference paragraphs 1 through 36 above.

38. Denied.

39. Denied.

40. Repeats and incorporates by reference paragraphs 1 through 39.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied. Also see Auriga's affirmative defenses and counterclaims.
47. Repeats and incorporates by reference paragraphs 1 through 46.
48. Denied, and refers to the Agreement for the pertinent terms thereof.
49. Denied.
50. Denied.
51. Auriga repeats and incorporates by reference paragraphs 1 through 50.
52. Denied.
53. Denied.
54. Denied.
55. Denied.
56. Denied.

AFFIRMATIVE DEFENSES

1. The claims of the Complaint fail to state a claim upon which relief can be granted.
2. The claims of the Complaint are barred by set-off by virtue of Carilène's material breaches and anticipatory repudiation set forth in the first through third counterclaims herein.
3. The claims of the Complaint are barred by Carilène's frustration of the purposes of the Agreement, and prevention of Auriga's performance.
4. The claims of the Complaint are barred by the doctrine of estoppel.
5. The claims of the Complaint are barred by the doctrine of unclean hands.
6. The claims of the Complaint are barred because Carilène contributed to the damages alleged.

WHEREFORE, the Complaint should be dismissed in its entirety, and Auriga should be awarded costs and disbursements, and such other relief that the Court deems just and proper.

COUNTERCLAIMS

Counterclaim Plaintiff Auriga, as and for its Counterclaims against Counterclaim Defendant Carilène, alleges:

PARTIES

1. Auriga is a corporation duly organized and existing under the laws of the State of Delaware, having a place of business at 5555 Triangle Parkway, Norcross, Georgia.

2. Carilène is a corporation existing under the laws of France, having a place of business at 7 rue du Chant des Oiseaux, 78360 Montesson, France.

JURISDICTION AND VENUE

3. The Court has diversity jurisdiction over the subject matter of this action by virtue of 28 U.S.C. §§ 1332(a) and (c), in that Auriga is a citizen of a State and Carilène is a citizen of a foreign state, and the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

4. The Court has personal jurisdiction over Carilène because Carilène: (a) transacts business in the State of New York; and (b) has entered into two agreements with Auriga described hereinafter, which are expressly governed by the laws of the State of New York, and whereby Carilène expressly submits itself to the jurisdiction of this Court for adjudication of any litigation arising under said agreements.

5. Venue is proper in this judicial district by virtue of 28 U.S.C. §§ 1391(a) and (c), and because Carilène has entered into two agreements with Auriga described hereinafter, whereby Carilène expressly submits itself to the venue of this Court for adjudication of any litigation arising under said agreements.

FACTS COMMON TO ALL COUNTERCLAIMS

6. Auriga is a company with expertise in developing, advertising, promoting, and marketing specialty pharmaceutical products.

7. Upon information and belief, Carilène is a wholesaler and distributor of bulk active pharmaceutical ingredients.

The Artificial Saliva Product and Agreement

8. On or about September 13, 2006, Auriga and Carilène entered into a written Licensing and Supply Agreement (“the Agreement”), whereby Carilène agreed to supply to Auriga a novel and unique product used to treat dry mouth (“the Product”), and Auriga agreed to take an exclusive license from Carilène to promote, market, and sell the Product in the United States.

9. The Product is a rehydration solution delivered in a pump spray that treats xerostomia (dry mouth caused by lack of sufficient saliva). Dry mouth can be caused by medical conditions such as diabetes, hypertension, and rheumatoid arthritis.

10. Under the Agreement, Carilène grants an exclusive license to Auriga to promote, market, and sell the Product in the United States, in exchange for Auriga’s commercially reasonable efforts to promote, market, and sell the Product, and Auriga’s payment of certain monetary amounts to Carilène.

11. The Agreement obligates Carilène to supply the Product to Auriga in sufficient quantities and in sufficient lead times to allow Auriga to commercialize the Product. In this regard, the Agreement obligates Carilène to deliver Auriga’s first order for the Product within 12 weeks after Auriga places an order.

12. Auriga placed its first order on or about September 26, 2006.

13. Carilène did not deliver the Product until on or about February 17, 2007.

14. Despite the foregoing, Carilène did not deliver Auriga’s first order for the Product until about 20 weeks after the order was placed. This eight (8)-week delay significantly impaired Auriga’s plans to market the Product.

15. The Agreement provides that the minimum batch size of the Product is 100,000 units, deliverable in two separate shipments on two separate dates within any twelve-month period. Auriga placed its initial order for a delivery of 50,000 units. Nonetheless, Carilène told Auriga that it would only fill orders of 100,000 units, forcing Auriga to purchase a 50% larger initial quantity and to divert financial resources from Auriga's plans to market the product.

16. The Agreement requires Carilène to provide commercially viable samples of the product to Auriga. The Agreement also requires Carilène to provide information and data reasonably required to commercialize and exploit the Product, including but not limited to such information and data relating to commercial samples of the Product.

17. Carilène prevented Auriga from commercializing and exploiting the Product by failing to provide Auriga with commercially viable samples of the Product, and by failing to provide the aforesaid information and data.

18. On October 16, 2007, Auriga provided Carilène written notice that Carilène's aforesaid actions or omissions constituted material breaches of the Agreement.

19. In a letter dated October 22, 2007, Auriga proposed that the parties have substantive discussions to resolve all issues. Carilène did not respond. In fact, Carilène attempted to terminate the Agreement without cause (*see* Ex. D of the Complaint).

20. Pursuant to the Agreement, Auriga has taken commercially reasonable steps to commence promotion, marketing, distribution, and sale of the Product. By its aforesaid conduct, however, Carilène has frustrated Auriga's efforts to do so.

The Hair-Growth Product and Agreement

21. On or about June 6, 2007, Auriga and Carilène entered into another written agreement. This agreement was entitled Licensing and Distribution Agreement ("the HG

Agreement”), whereby Carilène agreed to supply Auriga with a novel and unique product used to stimulate hair growth (“the Hair-Growth Product”).

22. The Agreement is premised on Carilène ownership of U.S. Patent No. 6,001,378 (“the ’378 patent”), entitled “Combinations of Peroxide Lipids and Organosilicon Compounds, Cosmetic and Dermatological Compositions Containing Same, and Uses Thereof, in Particular for Treating Alopecia,” which was filed on January 24, 1997. The term of the HG Agreement extends from the date the HG Agreement was executed until the expiration of the ’378 patent.

23. Under the HG Agreement, Carilène granted an exclusive license to Auriga to promote, market, and sell the Hair-Growth Product in the U.S., in exchange for Auriga’s commercially reasonable efforts to promote, market, and sell the Product, and Auriga’s payment to Carilène of certain scheduled license payments and a royalty on net sales.

24. The HG Agreement requires Carilène to provide Auriga with all the necessary information and clinical data concerning the Hair-Growth Product. In the U.S., clinical data demonstrating safety and effectiveness are required to obtain obligatory premarket approval of the Hair-Growth Product from the Food and Drug Administration (“FDA”). The FDA also requires substantiation of marketing claims for the Hair-Growth Product.

25. Carilène provided Auriga with certain marketing information that it had used previously in Europe. That marketing information stated that the Hair-Growth Product: (1) was clinically effective; and (2) was better than another hair-growth product on the market.

26. When Auriga requested data and information underlying these marketing claims, Carilène responded by saying “trust us, the product works.”

27. When Auriga asked for clinical data for the Hair-Growth Product, Carilène provided clinical data that did not substantiate the marketing claims previously voiced by Carilène and contained in the marketing information used in Europe.

28. Auriga also asked for “before and after” pictures from the clinical trial and the patient records generated during the clinical trial.

29. Carilène provided “before and after” pictures not from the clinical trial but from Carilène employees who allegedly used the Hair-Growth Product, and did not provide any patient records.

30. Auriga needed the “before and after” pictures and the patient records to satisfy the FDA’s premarket approval and claim substantiation requirements that Carilène had promised the Hair-Growth Product could meet.

31. On or about October 1, 2007, Auriga sent Carilène a letter notifying Carilène that it materially breached the HG Agreement by failing to provide the “clinical data or photos.”

32. Carilène never responded to Auriga’s October 1, 2007 letter.

33. Pursuant to the HG Agreement, Auriga has taken commercially reasonable steps to commence promotion and marketing of the Hair-Growth Product. By its aforesaid conduct, however, Carilène has frustrated Auriga’s efforts to do so.

FIRST COUNTERCLAIM

Breaches of the Artificial Saliva Agreement

34. Auriga repeats and realleges the allegations of paragraphs 1-33 above.

35. To the extent the Agreement is valid and enforceable, Carilène has materially breached the Agreement by failing to: (1) timely deliver the Product after the first order was placed; (2) ship Auriga the second half of its initial order of 100,000; (3) provide commercially viable samples to Auriga; and (4) provide the information and data reasonably required to commercialize and exploit the Product.

36. Auriga did not excuse Carilène from its performance obligations imposed by the Agreement, and Carilène is not otherwise excused from its obligations.

37. By virtue of, and as a result of, Carilène's breaches of the Agreement, Auriga has incurred substantial financial damages in the amount of at least \$75,000 and additional monetary damages.

SECOND COUNTERCLAIM

Anticipatory Repudiation of the Artificial Saliva Agreement

38. Auriga repeats and realleges the allegations of paragraphs 1-33 above.

39. Auriga did not excuse Carilène from its performance obligations imposed by the Agreement, and Carilène is not otherwise excused from its obligations.

40. Carilène repudiated the Agreement before the conclusion of its term.

41. By virtue of, and as a result of, Carilène's anticipatory repudiation of the Agreement, Auriga has been and is deprived of the benefits afforded to Auriga by the Agreement.

42. The benefits of the Agreement to Auriga are irreplaceable, in that the Product is a novel and unique pharmaceutical formulation that Auriga can not obtain from any other source.

43. Auriga is ready, willing, and able to continue performance of its obligations under the Agreement to the conclusion of the term.

44. By virtue of, and as a result of, Carilène's anticipatory repudiation of the Agreement, Auriga has suffered incalculable and irreparable harm, and incurred substantial financial damages in the amount of at least \$75,000 and additional monetary damages.

THIRD COUNTERCLAIM

Breach of the Implied Covenant of Good Faith and Fair Dealing of the Artificial Saliva Agreement

45. Auriga repeats and realleges the allegations of paragraphs 1-33 above.

46. Auriga and Carilène, by entering into the Agreement, impliedly covenanted and warranted to each other that each would use its' best efforts to effectuate the terms of the Agreement.

47. By intentionally frustrating the purpose of the Agreement as aforesaid, Carilène breached the covenant of good faith and fair dealing.

48. By virtue of, and as a result of, Carilène's breach of the covenant of good faith and fair dealing, Auriga has incurred substantial financial damages in the amount of at least \$75,000 and additional monetary damages.

FOURTH COUNTERCLAIM

Breaches of the Hair-Growth Agreement

49. Auriga repeats and realleges the allegations of paragraphs 1-33 above.

50. The HG Agreement is valid and enforceable. Carilène has committed material breaches of the HG Agreement including but not limited to failing to provide the clinical data, pictures, and information required for FDA approval and to substantiate the marketing claims as required by the HG Agreement that Carilène used to entice Auriga to enter the HG Agreement. This failure precluded Auriga from developing and promoting the Hair-Growth Product.

51. Auriga did not excuse Carilène from its performance obligations imposed by the HG Agreement, and Carilène is not otherwise excused from its obligations.

52. By virtue of, and as a result of, Carilène's aforesaid breaches of the HG Agreement, Auriga has incurred substantial financial damages in the amount of at least \$75,000 and additional monetary damages.

FIFTH COUNTERCLAIM

**Breach of the Implied Covenant of
Good Faith and Fair Dealing of the Hair-Growth Agreement**

53. Auriga repeats and realleges the allegations of paragraphs 1-33 above.

54. Auriga and Carilène, by entering into the HG Agreement, impliedly covenanted and warranted to each other that each would use its' best efforts to effectuate the terms of the HG Agreement.

55. By intentionally frustrating the purpose of the HG Agreement as aforesaid, Carilène breached the covenant of good faith and fair dealing.

56. By virtue of, and as a result of, Carilène's breach of the covenant of good faith and fair dealing, Auriga has incurred substantial financial damages in the amount of at least \$75,000 and additional monetary damages.

PRAYER FOR RELIEF

WHEREFORE, Auriga prays for relief, as follows:

A. On the first counterclaim, a judgment against Counterclaim Defendant Carilène for money damages in the sum and amount of at least \$75,000 and additional monetary damages, plus interest.

B. On the second counterclaim, and order enjoining Counterclaim Defendant Carilène to specifically perform its obligations under the Agreement to the conclusion of its term.

C. On the third counterclaim, a judgment against Counterclaim Defendant Carilène for money damages in the sum and amount of at least \$75,000 and additional monetary damages, plus interest.

D. On the fourth counterclaim, a judgment against Counterclaim Defendant Carilène for money damages in the sum and amount of at least \$75,000 and additional monetary damages, plus interest.

E. On the fifth counterclaim, a judgment against Counterclaim Defendant Carilène for money damages in the sum and amount of at least \$75,000 and additional monetary damages, plus interest.

- F. An award to Auriga of costs and disbursements associated with this action.
- G. Such other and further relief as the Court deems just and proper.

JURY DEMAND

Trial by jury is demanded by plaintiff on all issues so triable.

December 13, 2007

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